IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

IN RE: AFLIBERCEPT PATENT LITIGATION **This Document Relates to All Cases**	MDL No. 1:24-MD-3103-TSK

REGENERON PHARMACEUTICALS, INC.'S MOTION FOR GUIDANCE REGARDING TEMPORARY RESTRAINING ORDERS IN VIEW OF THE MAY 18, 2024 EXPIRATION OF REGULATORY EXCLUSIVITY FOR EYLEA®

Fifteen days remain until May 18, 2024, the date on which FDA may approve biosimilar copies of Eylea®. Unless the four biosimilar manufacturers against whom Regeneron has sought injunctive relief—*i.e.*, Mylan/Biocon, Formycon, Samsung Bioepis, and Celltrion—provide assurances to Regeneron and the Court that they will not disturb the status quo by launching their products before the Court adjudicates Regeneron's pending motions, Regeneron may suffer irreparable harm if that date passes without resolution of those motions. Regeneron has sought such assurances from each of those four Defendants; the Defendants have not yet provided them. Accordingly, Regeneron seeks guidance from the Court regarding the timing of temporary restraining order ("TRO") motions while the Court considers Regeneron's pending motions for permanent and preliminary injunctions.

As the Court noted in January, the clock is counting down to the expiry of Regeneron's regulatory exclusivity. When the clock hits zero on May 18, 2024, FDA may approve one or more of Defendants' biosimilar products. Dkt. 61 (Case No. 1:23-cv-00089-TSK) at 2.[1] FDA does *not* consider patent infringement in its approval decisions under the BPCIA; the statute instead presumes such matters will be resolved through litigation—either fully on the merits, or

[1] An identical order was filed in each of the Samsung, Celltrion, and Formycon cases.

temporarily in the form of preliminary injunction proceedings—before FDA approval occurs. 42 U.S.C. § 262(k)(7)(B), *id.* at § 262(*l*)(8)(B); *Amgen v. Apotex*, 827 F.3d 1052, 1063 (Fed. Cir. 2016) (noting the BPCIA "give[s] the parties and the district court time" to adjudicate issues ahead of "immediate market entry that could cause irreparable injury."). Thus, absent an injunction, one or more Defendants may begin marketing their infringing products on or after May 18, 2024—notwithstanding the Court's December 2023 opinion upholding the validity of Regeneron's '865 patent that is asserted as a basis for injunction against every Defendant here. Indeed, even Biocon—an adjudged infringer of the '865 patent—will be free to launch its product if it receives FDA approval and no current order of this Court prevents it from doing so. Any launch of an infringing product would alter the market irreversibly.

In order to ensure the preservation of the status quo, Regeneron contacted each of Biocon, Samsung, Celltrion, and Formycon to confirm that they will not launch their infringing products until this Court has had time to decide the pending motions for injunctive relief. None has agreed. Without assurances from all four Defendants, or a Court order providing injunctive relief, Regeneron anticipates it will need to file TRO motions no later than Tuesday, May 14, 2024—or on a date that the Court directs—to preserve the status quo and prevent harm while the Court considers Regeneron's motions for injunctive relief.[2]

In adjudicating the fully briefed injunction motions against these four Defendants, the Court need not await the forthcoming briefing of an injunction motion against Amgen, the fifth defendant in this MDL. Due in part to a pre-transfer order from the court in California, injunction briefing against Amgen has not yet occurred. Amgen, therefore, is differently situated from the

[2] The Court has authority to grant TROs without waiting for oppositions from Defendants or holding oral argument. *See ClearOne Advantage, LLC v. Kersen*, 2024 WL 69918, at *2 (D. Md. Jan. 5, 2024) ("A court may enter a TRO 'without full notice, even, under certain circumstances, ex parte.'" (quoting *Hoechst Diafoil Co. v. Nan Ya Plastics Corp.*, 174 F.3d 411, 422 (4th Cir. 1999))).

other four Defendants. Indeed, both Regeneron and Amgen have agreed there is no need for a hearing on injunction proceedings against Amgen until August 2024, and none of the other four Defendants have asserted that adjudication of Regeneron's pending motions should await injunction briefing involving Amgen. A TRO, in the first instance, cannot exceed fourteen days in duration, Fed. R. Civ. P. 65(b)(2), so Regeneron respectfully submits that even with a TRO, it will be necessary to adjudicate the motions against Biocon/Mylan, Samsung, Celltrion, and Formycon before a motion against Amgen can be briefed.

Resolving the fully briefed motions for injunctive relief before adjudicating a later motion against Amgen fully accords with the JPML's Order. That Order does not address whether any Defendant may launch its product before the Court adjudicates Regeneron's requests for injunctive relief, and does not require that all hearings in all cases take place at the same time. Instead, it recognizes the importance of ensuring consistency of "rulings as to claim construction, patent validity, and other issues," Dkt. 112-1 (Case No. 1:24-cv-39) at 2, a goal that is assured by the fact that this Court will now preside over all hearings, even if they do not take place on the same day. MDL scheduling orders routinely designate certain cases as "Track 1" cases and others as "Track 2" cases, to reflect differences in factual issues or procedural posture. *See, e.g.*, *In re: Insulin Pricing Litigation*, 2:23-md-03080, Dkt. 34 at 2-5 (D.N.J. December 6, 2023); *In re: National Prescription Opiate Litigation*, 1:17-md-2804, Dkt. 232, Slip op. at 6-8 (N.D. Ohio April 11, 2018). Here, the Defendants' respective timelines necessitate injunction hearings against Biocon/Mylan, Samsung, Celltrion, and Formycon on a first track, and Amgen on a second. After injunctive proceedings resolve the immediate threat of the launch of infringing products, Regeneron is not aware of any reason why all five cases could not proceed on the same schedule for ensuing discovery and other pre-trial matters.

Accordingly, Regeneron respectfully requests guidance from the Court regarding its preferred timing for TRO motions against Biocon/Mylan, Samsung, Celltrion and Formycon. Absent further instruction, Regeneron will plan to file TRO motions on Tuesday, May 14, 2024, but is happy to file the motions on any schedule that would better facilitate the Court's resolution by Friday, May 17, 2024.

Date: May 3, 2024

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CERTIFICATE OF SERVICE

I hereby certify that on May 3, 2024, I electronically transmitted the foregoing with the Court. Counsel of record for all parties will be served by electronic mail.

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